



DEPARTMENT OF HEALTH & HUMAN SERVICES

FDA/DMB HFA-305

Public Health Service

MAR 16 2000

0130 '00 APR -5 P1:50

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ref: FDA Docket No. 00V-0610  
Accession No. 99A1919-00/01/02  
00A0256

Mr. Christopher Feinauer  
Manager Business Development  
Insight Technology, Inc.  
3 Technology Drive  
Londonderry, New Hampshire 03053

Dear Mr. Feinauer:

In accordance with 21 CFR 1010.4(c)(1), notice is given that the petitions from Insight Technology Inc., dated August 31, October 20, 1999, and January 14, 2000, for a variance from certain requirements of 21 CFR 1040.10 and 1040.11 is hereby approved. This variance, under the conditions stated below, will allow the introduction into commerce of the Class IIIb, Laser Aiming Light AN/PAQ-4C and the Class IIIb Laser Aiming Module (LAM), models LAM-100, LAM-200, LAM-300, and LAM-400 manufactured by Insight Technology, Inc.

A. Variance Number

00V-0610

B. Effective Date

In accordance with 21 CFR 1010.4(c)(1), this variance shall become effective on the date of this letter.

C. Termination Date

This variance shall be terminated five (5) years from the date of this letter.

D. Product for Which Variance is Granted

This variance is granted for the infrared Class IIIb, Laser Aiming Light, model AN/PAQ-4C and the Class IIIb Laser Aiming Module (LAM), visible and IR models LAM-100, LAM-200, LAM-300, and LAM-400.

E. Provisions from Which Variance is Granted

This variance is granted from the following requirements of 21 CFR 1040.10 and 1040.11:

1. 21 CFR 1040.11(b)(3), which restricts the class of alignment laser products such as the AN/PAQ-4C, and the Laser Aiming Modules (LAM) to Class IIIa,
2. 21 CFR 1040.10(f)(3) which requires Class IIIb laser systems to incorporate remote interlock connectors,
3. 21 CFR 1040.10(f)(4) which requires class IIIb laser systems to incorporate key controls,

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4. 21 CFR 1040.10(f)(5) which requires Class IIIb laser systems to incorporate emission indicators that provide a visible or audible signal. This section also requires that indication be given sufficiently prior to emission to permit appropriate action to avoid exposure to laser radiation in excess of the accessible emission limits of Class I (1040.10(f)(5)(ii)). Also, this section requires that visible indicators be visible through laser protective eyewear designed for the applicable wavelength(s), (1040.10(f)(5)(iv)).
5. 21 CFR 1040.10(g)(2)(iii) which requires warning logotype labeling affixed to Class IIIb laser systems to have a white background with black lettering in positions 1, 2, and 3 of this label.

All other provisions of 21 CFR 1040.10 and 1040.11 remain applicable to the laser product.

F. Conditions under Which Variance is Granted

In lieu of the requirement referred to in Item E above, the following conditions shall apply to the Class IIIb, Laser Aiming Light (IAL) model AN/PAQ-4C and the Class IIIb Laser Aiming Module (LAM) models LAM-100, LAM-200, LAM-300, and LAM-400 visible and infrared laser aiming devices manufactured under this variance.

1. The sales of these laser aiming sights shall be restricted to government, military and law enforcement agencies under a direct purchase order from the agency and shall not be sold to individual law enforcement personnel.
2. The user information to be supplied with each laser weapon sight shall include:
  - a. Detailed written instructions on the radiation hazards of the laser sight and on its safe use including warnings against eye exposure ocular hazard distance while being used in a training program.
  - b. A statement that resale of these products is restricted to government, military, or law enforcement agencies under a direct purchase order and shall not be sold to individual law enforcement officers.
  - c. A statement that the batteries shall be removed when the product is not intended to operate to prevent unauthorized use.
  - d. A statement that it is also necessary and intended that the invisible beam emitted by these devices be viewed by the user through night vision equipment.
3. The product incorporates a normally off/momentarily on pressure switch that serves the function of both the emission indicator and beam attenuator within the intent of the regulations.
4. Advertising and sales literature used for promotion of this product will include a statement that the sale of these devices is restricted to government, military and law enforcement agencies through a direct purchase order.
5. Alternate labeling will include a black background with white lettering in positions 1, 2, and 3 of the warning logotype label.

G. Basis for Approval of Variance

The Center for Devices and Radiological Health has determined, in accordance with 21 CFR 1010.4(a), that these infrared aiming laser devices utilize alternate means for providing radiation safety or protection equal to that provided by products of similar design meeting all the requirements of the standard and/or that the specified requirements are not appropriate for laser products for this intended use.

The intended use of this product is by government, military or law enforcement agencies in the routine execution of their duties, and under conditions that could seriously compromise their safety should their position be revealed by a sound or a light or function of the product be impaired by delay of emission of the targeting beam or when preparing the product for operation.

H. Certification Label

The certification label required by 21 CFR 1010.2 shall be modified in accordance with 21 CFR 1010.4(d) to state, "Conforms to 21 CFR 1040, laser products, except as authorized by Variance 00V-0610 effective MAR 16 2000"

This variance action is available for public disclosure in the Dockets Management Branch, Food and Drug Administration. The variance will remain in effect until the termination date unless a determination is made that the variance should be amended or withdrawn, or the provisions of the standard from which the variance is granted are amended before the termination date.

Sincerely yours,



Lillian J. Gill  
Director  
Office of Compliance  
Center for Devices and  
Radiological Health

cc: FDA Dockets Management Branch, Docket No. 00V-0610